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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,033	07/22/2003	Pascal Sebastian Bailon	20917 US1	2294

151 7590 01/18/2005

HOFFMANN-LA ROCHE INC.  
PATENT LAW DEPARTMENT  
340 KINGSLAND STREET  
NUTLEY, NJ 07110

EXAMINER
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TRUONG, DUC

ART UNIT	PAPER NUMBER
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1711

DATE MAILED: 01/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/625,033

Applicant(s)

BAILON ET AL.

Examiner

Duc Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-67 is/are pending in the application.  
4a) Of the above claim(s) 27-50 and 53-67 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-26 is/are allowed.
- 6) ☒ Claim(s) 1-14, 51 and 52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>102703 and 033104</u> . | 6) <input type="checkbox"/> Other: ____  |

### **DETAILED ACTION**

Applicant's election with traverse of Group I in the reply filed on November 10, 2004 is acknowledged. The traversal is on the ground(s) that the claims in groups I, II, III, IV and V require common elements and do not require an additional search. This is not found persuasive because the search is based on different classifications of the groups and constitute an undue burden in that the search for one of the inventions do not involve the search of the others and no error in the requirements for the requirements have been pointed out by Applicant.

The requirement is still deemed proper and is therefore made FINAL.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Chem Abstract 134: 183490.

Chem Abstract 134: 183490 disclose the claimed formula in that R= methyl group, PAG= polyethylene glycol, R1=R2=hydrogen, A is activated leaving group and  $m+n=5$  ( $n=0$  and  $m=5$  or  $n=1$  and  $m=4$ )

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14, 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chem Abstract 134: 183490 or Iwasaki et al (4,670,417) or WO 0146291, both are of record on 1449.

Chem Abstract 134: 183490 discloses hydrophilic and lipophilic balanced microemulsion formulations of free form and/or conjugation stabilized therapeutic agents such as insulin using hexyl insulin conjugates with ethylene glycol 7 O-hexanoic of the formula.

The reference further discloses other forms of hydrophilic and lipophilic balanced microemulsions of free and/or conjugated drugs.

The Iwasaki reference discloses in Example 4, reactants and the steps of the process polyalkylene glycol acid ester having a leaving group is N-hydroxysuccinimidyl group (see cols 8-9, example 4).

The WO 01 46291 reference discloses a polymer comprising a water soluble and non-peptidic polymer backbone such as poly(alkylene glycol), and having at least one terminus of the structure (see claims 1-2, 10, 15, and 26-29) in that if Z=alkyl and X of the reference = O-A leaving group of the claimed formula then the formula in the reference is read on that of the claims.

Note that the reactants and the steps of the process have been disclosed at least in the Example 4.

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The disclosures of the references differ from the instant claims in that they do not disclose the broad claimed formula with the broad reactants under steps in the claimed process.

However, they do disclose the required reactants under the same or similar conditions to form the products of the claimed formula. Therefore, it would have been obvious to one of ordinary skill in the art to select reactants under conditions from the references within the limitations of the instant claims since they have been shown to be effective in a similar system and thus would have been expected to provide adequate results. There is no showing of unexpected results derived from said selections.

Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 52 is indefinite in the use of "leaving group is N-hydroxysuccinimidyl group 58" in that 58 is not determined.

Claims 15-26 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Duc Truong whose telephone number is 571-272-1081. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571-272-1078. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Ductruong', is positioned above the printed name.

DUCTRUONG  
PRIMARY EXAMINER

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